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ID

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/436,076	11/08/99	WAGNER	D 10861/011003

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EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	8

DATE MAILED: 08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/436,076	Applicant(s) Wagner et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Jun 26, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *40-42, 45, 49-53, 56, 59-62, and 64-66* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *40-42, 45, 49-53, 56, 59-62, and 64-66* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3&5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald R. Ewoldt in Group Art Unit 1644.

2. Applicant's amendment and response, filed 6/26/00 is acknowledged.

3. Applicant's election with traverse of Group II (claims 44, 55, 61, and 62) in Paper No. 7 is acknowledged. However, Applicant's traversal is rendered moot by Applicant's amending of claims 40, 42, 45, 49-51, 53, 56, and 59-60, and the cancellation of claims 39, 46-48, 57-58, and 63. All pending claims now read on the elected Group II and are being acted upon.

Claims 40-42, 45, 49-53, 56, 59-62, and 64-66 are pending and being acted upon.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 64-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed in claims 64-66, specifically: "a fusion protein comprising a P-selectin ligand or a fragment thereof and another molecule capable of inhibiting interaction between P-selectin and a ligand of P-selectin". The underlining is added emphasis.

Applicant's amendment, filed 6/26/00, asserts that no new matter has been added. However, the specification and claims as originally filed do not provide sufficient direction for the written description of the newly claimed limitations. For support of new claims, Applicant refers to page 8, last paragraph, through page 9, line 9, of the specification. However, this section offers no **specific** support for a fusion protein.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 40-42, 45, 49-50, and 64 are rejected under 35 U.S.C. 101

because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The asserted utility of the chimeric construct or fusion protein includes the prevention of restenosis. The disclosed examples include no references nor data concerning the prevention of said condition. Therefore, one skilled in the art at the time the invention was made could not assume that said condition could be prevented. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed for any method of preventing restenosis.

8. Claims 40-42, 45, 49-53, 56, 59-62, and 64-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of *any* method of treating or preventing restenosis, or treating or inhibiting atherosclerosis, using a "chimeric construct comprising a P-selectin ligand or a fragment thereof and another molecule capable of inhibiting interaction between P-selectin and a ligand of P-selectin" or *any* "fusion protein comprising a P-selectin ligand or a fragment thereof and another molecule capable of inhibiting interaction between P-selectin and a ligand of P-selectin" as *none* are disclosed in the specification. Additionally, the specification defines

a P-selectin ligand as any "moiety which binds P-selectin", fragments of said ligand are undefined and would thus include *any* fragment whether it binds P-selectin or not. The open language and lack of limitations would include an unlimited number of fragments including even single amino acids. *No* fusion proteins are disclosed in the specification and "[An]other molecule" is insufficiently defined, thus the open language and lack of limitations would include a virtually unlimited number of molecules and fusion proteins. One of skill in the art would therefore conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

9. Claims 40-42, 45, 49-53, 56, 59-62, and 64-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. The specification provides insufficient evidence that any "chimeric construct comprising a P-selectin ligand or a fragment thereof and another molecule capable of inhibiting interaction between P-selectin and a ligand of P-selectin" or "fusion protein comprising a P-selectin ligand or a fragment thereof and another molecule capable of inhibiting interaction between P-selectin and a ligand of P-selectin", can be used for the treatment or prevention of

restenosis or atherosclerosis in a mammal. In fact, *no* actual chimeric constructs or fusion proteins are disclosed in the specification. The disclosed examples therefore teach neither chimeric constructs nor fusion proteins, nor any uses thereof. Thus, the efficacy of treating or preventing any disease/condition with said chimeric constructs or fusion proteins cannot be assessed. Additionally, the examples fail to even mention restenosis and disclose only that atherosclerosis can be associated with P-selectin expression in certain gene knockout mouse models. One of skill in the art at the time the invention was made would therefore conclude that the treatment or prevention of restenosis or atherosclerosis in a mammal with the claimed chimeric constructs or fusion proteins has not been enabled.

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for undisclosed P-selectin ligand chimeric constructs or fusion proteins.

In view of the quantity of experimentation necessary because of the lack of any actual chimeric constructs or fusion proteins, and the lack of any working examples disclosing the use of any actual chimeric constructs or fusion proteins, it would take undue trials and errors to practice the claimed invention. See *in re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims

particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 45, 56, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The designation "PSGL-1" renders the claims indefinite because the abbreviation has not been defined.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 61-62 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Sako et al. (1993, IDS)

Sako et al. teaches a P-selectin glycoprotein ligand-1 (PSGL-1) fusion protein that is also a chimeric construct (human-bacteriophage) capable of inhibiting an interaction between P-selectin and a ligand of P-selectin, comprising a P-selectin ligand or a fragment thereof and a T7 phage protein (see particularly page 1181, column 2, last paragraph - page 1182 column 1, first paragraph).

The reference clearly anticipates the claimed chimeric construct of claims 61-62 and the fusion protein of claim 66.

14. Claims 61 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,412,123.

The '123 patent teaches a chimeric construct capable of inhibiting an interaction between P-selectin and a ligand of P-selectin, comprising a P-selectin ligand or a fragment thereof and another molecule, i.e., a P-selectin ligand-anti-inflammatory drug conjugate (see particularly column 4, lines 1-23).

The reference clearly anticipates the claimed invention.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.

Patent Examiner

Technology Center 1600

August 10, 2000

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